

**INFORMATION DISCLOSURE  
STATEMENT**

PTO-1449

ATTY. DOCKET NO.

39766-0131 RI-1D1

SERIAL NO.

10/028,410

APPLICANT Yves DUBAQUIE et al.

FILING DATE

December 19, 2001

GROUP: 1647

**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE

**FOREIGN PATENT DOCUMENTS**

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
BBB	WO 96/37216	11/28/1996	PCT	A61K	38/30, 38/35	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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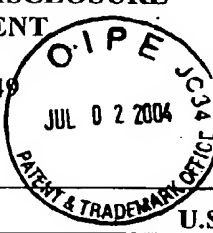

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Bridget E. Bunner

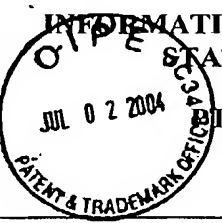
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EXAMINER'S INITIALS	PATENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE	
BBB	5,473,049	12-1995	Obermeier et al	530	303	—	
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						<input type="checkbox"/>	<input type="checkbox"/>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
BBB	Barnett and Owens, "Insulin analogues" <u>Lancet</u> 349 (9044): 47-51 (Jan. 4, 1997)						
1	Bass et al., "Hormone Phage: An Enrichment Method for variant proteins with altered binding properties", <u>Proteins: Structure, Function, and Genetics</u> 8 (4): 309-314 (1990)						
	Baxter & Martin, "Binding Proteins For Insulin-Like Growth Factors In Adult Rat Serum. Comparison With Other Human and Rat Binding Proteins" <u>Biochem &amp; Biophys Res. Comm.</u> 147(1):408-415 (1987)						
	Baxter, R., "The Insulin-Like Growth Factors and Their Binding Proteins" <u>Comp. Biochem. Physiol.</u> 91B(2): 229-235 (1988)						
BBB	Binkert et al., "Cloning, sequence analysis and expression of a cDNA encoding a novel insulin-like growth factor binding protein (IGFBP-2)" <u>EMBO Journal</u> 8: 2497-2502 (1989)						
EXAMINER <i>Bridget E. Ranner</i>			DATE CONSIDERED <i>8/11/2004</i>				

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BOB	Bornfeldt et al., "Binding and biological effects of insulin, insulin analogues and insulin-like growth factor in rat aortic smooth muscle cells. Comparison of maximal growth promoting activities" <u>Diabetologia</u> 34(5): 307-313 (May 1991)	
	Bowie et al., "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions" <u>Science</u> 247: 1306-1310 (1990)	
	Brange et al., "Designing insulin for diabetes therapy by protein engineering" <u>Current Opinion in Structural Biology</u> 1: 934-940 (1991)	
	Brange et al., "Monomeric insulins obtained by protein engineering and their medical implications" <u>Nature</u> 333 (6174) : 679-682 (Jun 16, 1988)	
	Brange, J., "Insulin Preparations" <u>Galenics of Insulin, The Physico-Chemical and Pharmaceutical Aspects of Insulin and Insulin Preparations</u> , New York: Springer-Verlag, pps. 17-40 (1987)	
	Brenner, S.E., "Errors in Genome Annotation" <u>Trends in Genetics</u> 15: 132-133 (1999)	
	Brewer et al., "Cloning, Characterization, and Expression of a Human Insulin-Like Growth Factor Binding Protein" <u>Biochem &amp; Biophys. Res. Comm.</u> 152(3): 1289-1297 (1988)	
	Brinkman et al., "Isolation and Characterization of a cDNA encoding the low molecular weight insulin-like growth factor binding protein (IBP-1)" <u>The EMBO J.</u> 7:2417-2423 (1988)	
	Cara et al., "An insulin-like growth factor I/insulin hybrid exhibiting high potency for interaction with the type I insulin-like growth factor and insulin receptors of placental plasma membranes" <u>Journal of Biological Chemistry</u> 265 (29):17820-17825 (Oct 15, 1990)	
	Chang et al., "Single-Step Solubilization and Folding of IGF-1 Aggregates From Escherichia coli" <u>Protein Folding: In Vivo and In Vitro</u> , American Chemical Society, Chapter 14, pps. 178-188 (1993)	
	Clackson et al., "A Hot Spot of Binding Energy in a Hormone-Receptor Interface" <u>Science</u> 267: 383-386 (1995)	
	Cunningham et al., "Engineering Human Prolactin to Bind to the Human Growth Receptor" <u>Science</u> 247:1461-1465 (1990)	
	DiCera, E., "Site-Specific Thermodynamics: Understanding Cooperativity in Molecular Recognition" <u>Chem. Rev.</u> 98: 1563-1591 (1998)	
	DiMarchi et al., "Synthesis of a fast-acting insulin analog based on structural homology with insulin-like growth factor-I" <u>Peptides: Chemistry and Biology</u> (Proceedings of the Twelfth American Peptide Symposium) J.A. Smith and J.E. River, eds., Leiden: ESCOM pps. 26-28 (1992)	
	Dodd et al., "Reversible Adsorption of soluble hexameric insulin onto the surface of insulin crystals cocrystallized with protamine: an electrostatic interaction" <u>Pharmaceutical Research</u> 12(1):60-68 (Jan 1995)	
BOB	Drejer, K., "The bioactivity of insulin analogues from in vitro receptor binding to in vivo glucose uptake" <u>Diabetes-Metabolism Reviews</u> 8(3): 259-285 (Oct 1992)	
EXAMINER <i>Bridget E. Bunner</i>	DATE CONSIDERED <i>8/11/2004</i>	

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

BOB Hober et al., "Disulfide Exchange Folding of Insulin-Like Growth Factor I" Biochemistry 31: 1749-1756 (1992)

Howey et al., "[Lys(B28), Pro(B29)]-Human Insulin: an Equipotent Analog of Human Insulin with Rapid Onset and Short Duration of Action" Diabetes (Abstract #1688) 40(Suppl 1): 423A (1991)

Hua, Qing-Hua et al., "Mini-proinsulin and Mini-IGF-I: Homologous Protein Sequence Encoding Non-homologous Structures" IBM 277:103-118 (1998)

Kang et al., "Comparison of subcutaneous soluble human insulin and insulin analogues (AspB9, Glu B27; Asp B10, Asp B28) on meal-related plasma glucose excursions in type I diabetic subjects: Diabetes Care 14(7): 571-577 (Jul 1991)

Kelley et al., "Analysis of the Factor VIIa Binding Site on Human Tissue Factor: Effects of Tissue Factor Mutations on the Kinetics and Thermodynamics of Binding" Biochemistry 34(33): 10383-10392 (1995)

Kunkel et al., "Efficient site-directed mutagenesis using uracil-containing DNA" Methods in Enzymology 204: 125-139 (1991)

Lassalle et al., "ESM-1 is a novel human endothelial cell-specific molecule expressed in lung and regulated by cytokines" Journal of Biological Chemistry 271: 20458-20464 (1996)

Leung et al., "Growth hormone receptor and serum binding protein: purification, cloning and expression" Nature 330:537-543 (1987)

Lowman et al., "Selecting High-Affinity Binding Proteins by Monovalent Phage Display" Biochemistry 30 (45): 10832-10838 (1991)

Lowman et al., "Exchanging Interleukin-8 and Melanoma Growth-stimulating Activity Receptor Binding Specificities" Journal of Biological Chemistry 271(24): 14344-14352 (1996)


Lowman et al., "Mutational Analysis and Protein Engineering of Receptor-Binding Determinates in Human Placental Lactogen" Journal of Biological Chemistry 266(17): 10982-10988 (Jun 15, 1991)

Martin & Baxter "Insulin-like Growth Factor-Binding Protein from Human Plasma. Purification and Characterization" Journal of Biological Chemistry 261(19): 8754-8760 (1986)

BOB Ngo et al., "Computational Complexity, Protein Structure Prediction and the Levinthal Paradox" The Protein Folding Problem and Tertiary Structure Prediction Merz & Le Grand, Boston: Birkhauser, pps. 491-495 (1994)

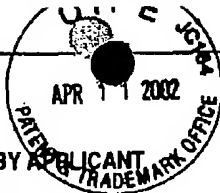
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Bob	Oh et al., "Synthesis and characterization of insulin-like growth factor-binding protein (IGFBP)-7 Recombinant human mac25 protein specifically binds IGF-I and -II <u>Journal of Biological Chemistry</u> 271: 30322-30325 (1996)	
<hr/>	Powell et al., "Characterization of insulin-like growth factor-binding protein-3 in chronic renal failure serum" <u>Pediatric Research</u> 33(2):136-143 (Feb 1993)	
Bob	Rinderknecht and Humbel "The Amino Acid Sequence of Human Insulin-Like Growth Factor I and It's Structural Homolgy With Proinsulin" <u>Journal of Biological Chemistry</u> 253(8): 2769-2776 (1978)	
<hr/>	Sliker and Sundell, "Modifications in the 28-29 position of the insulin B-chain alter binding to the IGF-I receptor with minimal effect on insulin receptor binding" <u>Diabetes</u> (Abstract #670) 40(suppl. 1): 168A (1991)	
<hr/>	Swisshelm et al., "Enhanced expression of an insulin growth factor-like binding protein (mac25) in senescent human mammary epithelial cells and induced expression with retinoic acid" <u>Proc. Natl. Acad. Sci.</u> 92: 4472-4476 (1995)	
<hr/>	Weiss et al., "Heteronuclear 2D NMR studies of an engineered insulin monomer: assignment and characterization of the receptor-binding surface by selective 2H and 13C labeling with application to protein design" <u>Biochemistry</u> 30(30): 7373-7389 (1991)	
<hr/>	Wolpert et al., "Identification of an insulin analog with enhanced growth effect in aortic smooth muscle cells" <u>Diabetes</u> 39 (Suppl. 1): 140A (1990)	
<hr/>	Wood et al., "Cloning and expression of the growth hormone-dependent insulin-like growth factor-binding protein" <u>Molecular Endocrinology</u> 2: 1176-1185 (1988)	
Bob	Yamauchi et al., "Purification and molecular cloning of prostacyclin-stimulating factor from serum-free conditioned medium of human diploid fibroblast cells" <u>Biochemical Journal</u> 303(Part 2): 591-598 (1994)	
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Patent and Trademark OfficeDocket No.  
P1712R1-1D1Serial No.  
10/028,410Applicant  
Dubaguie et al.Filing Date  
19 Dec 2001Group  
Unknown 1647

## LIST OF DISCLOSURES CITED BY APPLICANT

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## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
beb	* 1	5,077,276	31.12.91	Ballard, F. et al.	514	2
	* 2	5,106,832	21.04.92	Froesch et al.	514	3
	* 3	5,164,370	17.11.92	Ballard, F. et al.	514	3
	* 4	5,273,961	28.12.93	Clark	514	8
	* 5	5,470,828	28.11.95	Ballard et al.	514	12
	* 6	5,514,646	07.05.96	Chance et al.	514	12
	* 7	5,565,428	15.10.96	Clark et al.	514	12
	* 8	5,714,460	03.02.98	Gluckman et al.	514	3
	* 9	5,741,776	21.04.98	Clark et al.	514	12
	* 10	5,750,373	12.05.98	Garrard et al.	435	69.4
	* 11	5,821,047	13.10.98	Garrard et al.	435	5
	* 12	5,834,250	10.11.98	Wells et al.	435	7.1
	* 13	5,891,722	06.04.99	Fuks et al.	435	346
	* 14	5,985,830	16.11.99	Acott et al.	514	12
beb	* 15	5,994,303	30.11.99	Arrhenius-Nyberg et al.	514	12

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes	No
beb	* 16	214,826	18.03.87	EPO			
	* 17	742,228	13.11.96	EPO			
	* 18	965,596	22.12.99	EPO			
	* 19	WO 00/20023	13.04.00	PCT			
	* 20	WO 00/23469	27.04.00	PCT			
	* 21	WO 89/05822	29.06.89	PCT			
	* 22	WO 94/04569	03.03.94	PCT			
	* 23	WO 96/33216	24.10.96	PCT			
	* 24	WO 97/39032	23.10.97	PCT			
	* 25	WO 98/45427	15.10.98	PCT			
	* 26	WO 98/56406	17.12.98	PCT			
beb	* 27	WO 99/32620	01.07.99	PCT (TRANSLATION ATTACHED)			

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

beb	* 28	Bach and Rechler, "Insulin-like Growth Factor Binding Proteins" <u>Diabetes Reviews</u> 3:38-61 (1995)
beb	* 29	Bagley et al., "A key functional role for the insulin-like growth factor 1 N-terminal pentapeptide" <u>Biochemical Journal</u> 259(3):665-671 (May 1, 1989)
beb	* 30	Bar et al., "Tissue localization of perfused endothelial cell IGF binding protein is markedly altered by association with IGF-I" <u>Endocrinology</u> 127(6):3243-3245 (1990)

Examiner

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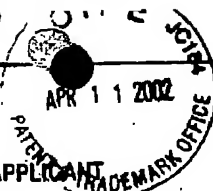
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(Use several sheets if necessary)

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

Bob	* 31	Baron et al., "Dexamethasone acts locally to inhibit longitudinal bone growth in rabbits" <u>American Journal of Physiology</u> 263(3 Pt 1):E489-E492 (Sep 1992)
	* 32	Barreca et al., "Short stature associated with high circulating insulin-like growth factor (IGF)-binding protein-1 and low circulating IGF-II: effect of growth hormone therapy" <u>Journal of Clinical Endocrinology &amp; Metabolism</u> 83(10):3534-3541 (Oct 1998)
	* 33	Batch et al., "Abnormal regulation of insulin-like growth factor binding proteins in adolescents with insulin-dependent diabetes" <u>Journal of Clinical Endocrinology &amp; Metabolism</u> 73(5):964-968 (Nov 1991)
	* 34	Baxter et al., "Recommendations for nomenclature of the insulin-like growth factor binding protein superfamily" <u>Endocrinology</u> 139(10):4036 (Oct 1998)
	* 35	Baxter et al., "Structural determinants for binary and ternary complex formation between insulin-like growth factor-I (IGF-I) and IGF binding protein-3" <u>Journal of Biological Chemistry</u> 267(1):60-65 (Jan 5, 1992)
	* 36	Bayne et al., "Structural analogs of human insulin-like growth factor I with reduced affinity for serum binding proteins and the type 2 insulin-like growth factor receptor" <u>Journal of Biological Chemistry</u> 263:6233-6239 (1988)
	* 37	Bayne et al., "The C region of human insulin-like growth factor (IGF) I is required for high affinity binding to the type 1 IGF receptor" <u>Journal of Biological Chemistry</u> 264(19):11004-11008 (1988)
	* 38	Bayne et al., "The roles of tyrosines 24, 31, and 60 in the high affinity binding of insulin-like growth factor-I to the type 1 insulin-like growth factor receptor" <u>Journal of Biological Chemistry</u> 265(26):15648-15652 (Sep 15, 1990)
	* 39	Berek et al., "Insulin treatment normalizes reduced free insulin-like growth factor-I concentrations in diabetic children" <u>Clinical Endocrinology</u> 45(3):321-326 (Sep 1996)
	* 40	Berek et al., "Regulation of the insulin-like growth factor system by acute acidosis" <u>Endocrinology</u> 137(6):2238-2245 (Jun 1996)
	* 41	Blum et al., "Growth hormone resistance and inhibition of somatomedin activity by excess of insulin-like growth factor binding protein in uraemia" <u>Pediatric Nephrology</u> 5(4):539-544 (Jul 1991)
	* 42	Blum, W., "Insulin-like growth factors (IGFs) and IGF binding proteins in chronic renal failure: evidence for reduced secretion of IGFs" <u>Acta Paediatr. Scand.</u> 379(Suppl):24-31 (1991)
	* 43	Bogan and Thorn, "Anatomy of hot spots in protein interfaces" <u>Journal of Molecular Biology</u> 280(1):1-9 (Jul 3, 1998)
	* 44	Brems et al., "Altering the association properties of insulin by amino acid replacement" <u>Protein Engineering</u> 5(6):527-533 (1992)
	* 45	Cascieri et al., "Mutants of human insulin-like growth factor I with reduced affinity for the type 1 insulin-like growth factor receptor" <u>Biochemistry</u> 27(9):3229-3233 (May 3, 1988)
	* 46	Cascieri et al., "Structural analogs of human insulin-like growth factor (IGF) I with altered affinity for type 2 IGF receptors" <u>Journal of Biological Chemistry</u> 264:2199-2202 (1989)
	* 47	Chernauek et al., "Proteolytic cleavage of insulin-like growth factor binding protein 4 (IGFBP-4). Localization of cleavage site to non-homologous region of native IGFBP-4" <u>Journal of Biological Chemistry</u> 270(19):11377-11382 (May 12, 1995)
	* 48	Clark and Robinson, "Up and down the growth hormone cascade" <u>Cytokine &amp; Growth Factor Reviews</u> 7(1):65-80 (Jun 1996)
	* 49	Clemmons et al., "Competition for binding to insulin-like growth factor (IGF) binding protein-2, 3, 4, and 5 by the IGFs and IGF analogs" <u>Endocrinology</u> 131(2):890-895 (Aug 1992)
Bob	* 50	Clemmons et al., "Discrete Alterations of the Insulin-like Growth Factor I Molecule Which Alter Its Affinity for Insulin-like Growth Factor-binding Proteins Result in Changes in Bioactivity" <u>Journal of Biological Chemistry</u> 265(21):12210-12216 (1990)

Examiner

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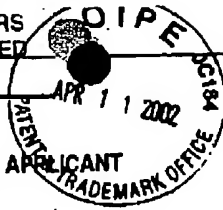
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Sheet 3 of 7

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(Use several sheets if necessary)

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

51	Clemmons, D., "Insulin-like growth factor binding proteins and their role in controlling IGF actions" <u>Cytokine &amp; Growth Factor Reviews</u> 8(1):45-62 (Mar 1997)
52	Cohick and Clemmons, "The insulin-like growth factors" <u>Annu. Rev. Physiol.</u> 55:111-153 (1993)
53	Conover, "Potentiation of insulin-like growth factor (IGF) action by IGF-binding protein-3: studies of underlying mechanism" <u>Endocrinology</u> 130(6):3191-3199 (Apr 1992)
54	Conover, C., "Insulin-like growth factor binding protein proteolysis in bone cell models" <u>Progress in Growth Factor Research</u> 6(2-4):301-309 (1995)
55	Cooke et al., "Solution Structure of Human Insulin-Like Growth Factor I: A Nuclear Magnetic Resonance and Restrained Molecular Dynamics Study" <u>Biochemistry</u> 30:5484-5491 (1991)
56	Cox et al., "Recombinant human insulin-like growth factor (IGF)-binding protein-1 inhibits somatic growth stimulated by IGF-I and growth hormone in hypophysectomized rats" <u>Endocrinology</u> 135(5):1913-1920 (1994)
57	Crown and Holly, "The insulin-like growth factor system in critical illness: pathophysiology and therapeutic potential" <u>Clinical Nutrition</u> 14:321-328 (1995)
58	Cunningham and Wells, "Comparison of a structural and a functional epitope" <u>Journal of Molecular Biology</u> 234(3):554-563 (Dec 5, 1993)
59	Cunningham and Wells, "High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis" <u>Science</u> 244:1081-1085 (1989)
60	Cunningham et al., "Production of an Atrial Natriuretic Peptide Variant that is Specific for Type A Receptor" <u>EMBO Journal</u> 13(11):2508-2515 (1994)
61	Davidson, M., "Effect of growth hormone on carbohydrate and lipid metabolism" <u>Endocrine Reviews</u> 8(2):115-131 (May 1987)
62	DeWolf et al., "Solution structure of a mini IGF-1" <u>Protein Science</u> 5(11):2193-2202 (Nov 1996)
63	Dubaquie and Lowman, "Total Alanine-Scanning Mutagenesis of Insulin-Like Growth Factor I (IGF-I) Identifies Differential Binding Epitopes for IGFBP-1 and IGFBP-3" <u>Biochemistry</u> 38(20):6386-6396 (1999)
64	Fuller et al., "Stimulation of Cardiac Protein Synthesis by Insulin-like Growth Factors" <u>Biochemical Society Transactions</u> 19:277S (1991)
65	Garrett et al., "Crystal structure of the first three domains of the type-1 insulin-like growth factor receptor" <u>Nature</u> 394(6691):395-399 (Jul 23, 1998)
66	Guler et al., "Effects of recombinant insulin-like growth factor I on insulin secretion and renal function in normal human subjects" <u>Proc. Natl. Acad. Sci. USA</u> 86:2868-2872 (April 1989)
67	Guler et al., "Insulin-like growth factor I increases glomerular filtration rate and renal plasma flow in man" <u>Acta Endocrinologica</u> 121:101-106 (1989)
68	Hall et al., "Serum levels of the low molecular weight form of insulin-like growth factor binding protein in healthy subjects and patients with growth hormone deficiency, acromegaly and anorexia nervosa" <u>Acta Endocrinologica</u> 118(3):321-326 (Jul 1988)
69	Hammerman and Miller, "The growth hormone insulin-like factor axis in kidney revisited" <u>Am. J. Physiol.</u> 265:F1-F14 (1993)
70	Hammerman and Miller, "Therapeutic use of growth factors in renal failure" <u>J. Am. Soc. Nephrol.</u> 5:1-11 (1994)

Examiner

Bridget C. Burner

Date Considered

7/7/03

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Dubaquie et al.

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19 Dec 2001

Group

Unknown/647

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- 71 Heding et al., "Biosensor measurement of the binding of insulin-like growth factors I and II and their analogues to the insulin-like growth factor-binding protein-3" Journal of Biological Chemistry 271(24):13948-13952 (Jun 14, 1996)
- 72 Hirschberg et al., "Effects of insulin-like growth factor I on renal function in normal men" Kidney International 43:387-397 (1993)
- 73 Rise et al., "Influence of circulating insulin-like growth factor-I compared with that of intrarenal insulin-like growth factor-I on proximal nephron receptor density in rats" Clinical Science 83:233-239 (1992)
- 74 Hoogenberg et al., "Effect of growth hormone and insulin-like growth factor I on urinary albumin excretion: studies in acromegaly and growth hormone deficiency" Acta Endocrinologica 129:151-157 (1993)
- 75 Horber et al., "Differential effects of prednisone and growth hormone on fuel metabolism and insulin antagonism in humans" Diabetes 40(1):141-149 (Jan 1991)
- 76 Hua et al., "Native and non-native structure in a protein-folding intermediate: spectroscopic studies of partially reduced IGF-I and an engineered alanine model" Journal of Molecular Biology 259(2):297-313 (Jun 7, 1996)
- 77 Ikkos et al., "Glomerular filtration rate and renal plasma flow in acromegaly" Acta Endocrinologica 21:226-236 (1956)
- 78 Jansson et al., "Structural Changes in Insulin-Like Growth Factor (IGF) I Mutant Proteins Affecting Binding Kinetic Rates to IGF Binding Protein 1 and IGF-I Receptor" Biochemistry 36:4108-4117 (1997)
- 79 Jansson et al., "The Insulin-like Growth Factor (IGF) Binding Protein 1 Binding Epitope on IGF-I Probed by Heteronuclear NMR Spectroscopy and Mutational Analysis" The Journal of Biological Chemistry 273(38):24701-24707 (September 18, 1998)
- 80 Joly et al., "Overexpression of Escherichia coli Oxidoreductases Increases Recombinant Insulin-Like Growth Factor-I Accumulation." Proc. Natl. Acad. Sci. USA 95:2773-2777 (Mar 1998)
- 81 Jones et al., "Insulin-Like Growth Factors and Their Binding Proteins: Biological Actions" Endocrine Reviews 16(1):3-34 (1995)
- 82 Kalus et al., "Structure of the IGF-binding domain of the insulin-like growth factor-binding protein-5 (IGFBP-5): implications for IGF and IGF-I receptor interactions" EMBO Journal 17(22):6558-6572 (Nov 16, 1998)
- 83 Kanety et al., "Long-term treatment of Laron type dwarfs with insulin-like growth factor-1 increases serum insulin-like growth factor-binding protein-3 in the absence of growth hormone activity" Acta Endocrinologica 128(2):144-149 (Feb 1993)
- 84 King et al., "Production and characterization of recombinant insulin-like growth factor-I (IGF-I) and potent analogues of IGF-I, with Gly or Arg substituted for Glu<sup>3</sup>, following their expression in Escherichia coli as fusion proteins" Journal of Molecular Endocrinology 8(1):29-41 (Feb 1992)
- 85 Kristensen, C. et al., "Alanine Scanning Mutagenesis of Insulin" The Journal of Biological Chemistry 272(20):12978-12983 (May 16, 1997)
- 86 Kupfer et al., "Enhancement of the anabolic effects of growth hormone and insulin-like growth factor I by use of both agents simultaneously" J. Clin Invest. 91:391-396 (1993)
- 87 Lee et al., "IGF binding proteins in growth-retarded children with chronic renal failure" Pediatric Research 26(4):308-315 (Oct 1989)
- 88 Lee et al., "Insulin-Like Growth Factor (IGF) Binding Protein Complementary Deoxyribonucleic Acid from Human HEP G2 Hepatoma Cells: Predicted Protein Sequence Suggests an IGF Binding Domain Different from Those of the IGF-I and IGF-II Receptors" Mol. Endocrinol. 2(5):404-411 (1988)
- 89 Lee et al., "Insulin-like growth factor binding protein-1: recent findings and new directions" Proceedings of the Society for Experimental Biology & Medicine 216(3):319-357 (Dec 1997)
- 90 Lewitt et al., "Bioavailability of insulin-like growth factors (IGFs) in rats determined by the molecular distribution of human IGF-binding protein-3" Endocrinology 133:1797-1802 (1993)

Examiner

Bridget E. Burner

Date Considered

7/7/03

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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10/028,410

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

COPY OF PAPERS  
ORIGINAL FILEDApplicant  
Dubaque et al.Filing Date  
19 Dec 2001Group  
Unknown

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

* 91	Lewitt et al., "Insulin-like Growth Factor-Binding Protein-1 Modulates Blood Glucose Levels" <u>Endocrinology</u> 129(4):2254-2256 (1991)
* 92	Liu et al., "Characterization of insulin-like growth factor-binding proteins in human serum from patients with chronic renal failure" <u>Journal of Clinical Endocrinology &amp; Metabolism</u> 70(3):620-628 (Mar 1990)
* 93	Loddick et al., "Displacement of insulin-like growth factors from their binding proteins as a potential treatment for stroke" <u>Proc. Natl. Acad. Sci. USA</u> 95(4):1894-1898 (Feb 17, 1998)
* 94	Lowman and Wells, "Affinity maturation of human growth hormone by monovalent phage display" <u>Journal of Molecular Biology</u> 234(3):564-578 (1993)
* 95	Lowman et al., "Molecular mimics of insulin-like growth factor I (IGF-I) for inhibiting IGF-I: IGF-binding protein interactions" <u>Biochemistry</u> 37(25):8870-8878 (1998)
* 96	Lowman, H., "Phage display of peptide libraries on protein scaffolds" <u>Methods in Molecular Biology</u> , Chapter 24, 87:249-264 (1998)
* 97	Magee et al., "Insulin-like growth factor I and its binding proteins: a study of the binding interface using B-domain analogues" <u>Biochemistry</u> 38(48):15863-15870 (Nov 30, 1999)
* 98	Manes et al., "Functional epitope mapping of insulin-like growth factor I (IGF-I) by Anti-IGF-I monoclonal antibodies" <u>Endocrinology</u> 138(3):905-915 (1997)
* 99	Martin and Baxter, "Regulation and actions of the insulin-like growth factor binding proteins" <u>Current Opinion in Endocrinology and Diabetes</u> pps. 16-21 (1994)
*100	McCarthy et al., "Cortisol inhibits the synthesis of insulin-like growth factor-I in skeletal cells" <u>Endocrinology</u> 126(3):1569-1575 (Mar 1990)
*101	McInnes and Sykes, "Growth factor receptors: structure, mechanism, and drug discovery" <u>Biopolymers</u> 43(5):339-366 (1997)
*102	Miller et al., "Effects of IGF-I on renal function in end-stage chronic renal failure" <u>Kidney International</u> 46:201-207 (1994)
*103	Moses, A., "Recombinant insulinlike growth factor-I as therapy in states of altered carbohydrate homeostasis" <u>Current Opinion in Endocrinology and Diabetes</u> 4:16-25 (1997)
*104	Murphy et al., "Phenotypic manifestations of insulin-like growth factor binding protein-1 (IGFBP-1) and IGFBP-3 overexpression in transgenic mice" <u>Progress in Growth Factor Research</u> 6(2-4):425-432 (s 1995)
*105	Nakagawa, S. et al., "Role of the Phenylalanine B25 Side Chain in Directing Insulin Interaction with Its Receptor" <u>The Journal of Biological Chemistry</u> 261(16):7332-7341 (June 5, 1986)
*106	O'Shea and Layish, "Growth hormone and the kidney: a case presentation and review of the literature" <u>J. Am. Soc. Nephrol.</u> 3:157-161 (1992)
*107	O'Shea et al., "Effects of IGF-I on renal function in patients with chronic renal failure" <u>Am. J. Physiol.</u> 264:F917-F922 (1993)
*108	Oh et al., "Characterization of the affinities of insulin-like growth factor (IGF)-binding proteins 1-4 for IGF-I, IGF-II, IGF-I/insulin hybrid, and IGF-I analogs" <u>Endocrinology</u> 132:1337-1344 (1993)
*109	Peterkofsky et al., "Elevated Activity of Low Molecular Weight Insulin-Like Growth Factor-Binding Proteins in Sera of Vitamin C-Deficient and Fasted Guinea Pigs" <u>Endocrinology</u> 128(4):1769-1779 (1991)
*110	Powell et al., "Characterization of insulin-like growth factor binding protein-3 in chronic renal failure serum" <u>Pediatric Research</u> 33(2):136-143 (Feb 1993)

Examiner

Date Considered

Budget E. Burner

7/7/03

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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P1712R1-1D1

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## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Patent and Trademark Office

COPY OF PAPERS  
ORIGINAL FILED

Applicant

Dubaquie et al.

Filing Date

19 Dec 2001

Group

Unknown 1647

## OTHER DISCLOSURES (including Author, Title, Date, Pertinent Pages, etc.)

*111	Powell et al., "Modulation of growth factors by growth hormone in children with chronic renal failure." <u>Kidney International</u> 51(6):1970-1979 (Jun 1997)
*112	Powell et al., "Serum concentrations of insulin-like growth factor (IGF)-1, IGF-2 and unsaturated somatomedin carrier proteins in children with chronic renal failure" <u>American Journal of Kidney Diseases</u> 10(4):287-292 (Oct 1987)
*113	Quigley and Baum, "Effects of growth hormone and insulin-like growth factor I on rabbit proximal convoluted tubule transport" <u>J. Clin. Invest.</u> 88:368-374 (1991)
*114	Rajkumar et al., "Growth retardation and hyperglycemia in insulin-like growth factor binding protein-1 transgenic mice" <u>Endocrinology</u> 136(9):4029-4034 (Sep 1995)
*115	Rosenfeld et al., "IGF-1 treatment of syndromes of growth hormone insensitivity" <u>The insulin-like growth factors and their regulatory proteins</u> , Baxter et al. eds., Amsterdam:Excerpta Medica pps. 457-463 (1994)
*116	Ross et al., "Critically ill patients have high basal growth hormone levels with attenuated oscillatory activity associated with low levels of insulin-like growth factor-I" <u>Clinical Endocrinology</u> 35(1):47-54 (Jul 1991)
*117	Sapir et al., "The role of alanine and glutamine in steroid-induced nitrogen wasting in man" <u>Clinical Science &amp; Molecular Medicine</u> 53(3):215-220 (Sep 1977)
*118	Scharf et al., "Insulin-like growth factor-I serum concentrations and patterns of insulin-like growth factor binding proteins in patients with chronic liver disease" <u>Journal of Hepatology</u> 25(5):689-699 (Nov 1996)
*119	Shmueli et al., "High insulin-like growth factor binding protein 1 levels in cirrhosis: link with insulin resistance" <u>Hepatology</u> 24(1):127-133 (Jul 1996)
*120	Simmons et al., "Increased proteolysis. An effect of increases in plasma cortisol within the physiologic range" <u>Journal of Clinical Investigation</u> 73(2):412-420 (Feb 1984)
*121	Simpson et al., "Insulin-like growth factor-I and diabetes. A review" <u>Growth Hormone and IGF Research</u> 8:83-95 (1998)
*122	Slieker et al., "Insulin and IGF-I Analogs: Novel Approaches to Improved Insulin Pharmacokinetics" <u>Adv. Experimental Med. Biol.</u> 343:25-32 (1994)
*123	Terasawa et al., "Solution structure of human insulin-like growth factor II; recognition sites for receptors and binding proteins" <u>EMBO Journal</u> 13(23):5590-5597 (Dec 1, 1994)
*124	Thrallkill et al., "Dual hormonal replacement therapy with insulin and recombinant human insulin-like growth factor (IGF)-I in insulin-dependent diabetes mellitus: effects on the growth hormone/IGF/IGF-binding protein system" <u>Journal of Clin. Endocrinol. &amp; Metab.</u> 82(4):1181-1187 (Apr 1997)
*125	Tomas et al., "Insulin-like growth factor-I (IGF-I) and especially IGF-I variants are anabolic in dexamethasone-treated rats" <u>Biochemical Journal</u> 282(Pt 1):91-97 (Feb 15, 1992)
*126	Tonshoff et al., "Decreased hepatic insulin-like growth factor (IGF)-I and increased IGF binding protein-1 and -2 gene expression in experimental uremia" <u>Endocrinology</u> 138(3):938-946 (Mar 1997)
*127	Tonshoff et al., "Insulin-like growth factors (IGF) and IGF binding proteins in children with chronic renal failure" <u>Progress in Growth Factor Research</u> 6(2-4):481-491 (1995)
*128	Tonshoff et al., "Serum insulin-like growth factors (IGFs) and IGF binding proteins 1, 2, and 3 in children with chronic renal failure: relationship to height and glomerular filtration rate" <u>Journal of Clinical Endocrinology &amp; Metabolism</u> 80(9):2684-2691 (Sep 1995)
*129	Tonshoff et al., "Serum insulin-like growth factors and their binding proteins in children with end-stage renal disease" <u>Pediatric Nephrology</u> 10(3):269-274 (Jun 1996)
*130	Torres et al., "Solution structure of human insulin-like growth factor II. Relationship to receptor and binding protein interactions" <u>Journal of Molecular Biology</u> 248(2):385-401 (Apr 28, 1995)

Examiner

Bridget E. Bunner

Date Considered

7/7/03

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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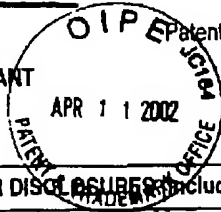
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FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P1712R1-1D1Serial No.  
10/028,410

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant  
Dubaquie et al.Filing Date  
19 Dec 2001Group  
Unknown 1647

## OTHER DISCLOSURES (including Author, Title, Date, Pertinent Pages, etc.)

- 131 Trainer et al., "Pyridostigmine partially reverses dexamethasone-induced inhibition of the growth hormone response to growth hormone-releasing hormone" Journal of Endocrinology 134(3):513-517 (Sep 1992)
- 132 Ullrich et al., "Insulin-like growth factor I receptor primary structure: comparison with insulin receptor suggests structural determinants that define functional specificity" EMBO Journal 5(10):2503-2512 (1986)
- 133 Umpleby et al., "Effects of Insulin-like Growth Factor-I (IGF-I), Insulin and Combined IGF-I-insulin Infusions on Protein Metabolism in Dogs" Eur. J. Clin. Invest. 24:337-344 (1994)
- 134 Underwood et al., "IGFs: Function and Clinical Importance 6 Therapy With Recombinant Human Insulin-like Growth Factor I in Children With Insensitivity to Growth Hormone and in catabolic conditions" J. Internal Med. 234:571-577 (1993)
- 135 Walker et al., "Stimulation of statural growth by recombinant insulin-like growth factor I in a child with growth hormone insensitivity syndrome (Laron type)" J. Pediatr. 121:641-646 (1992)
- 136 Wells, J. A., "Additivity of Mutational Effects in Proteins" Biochemistry 29(37):8509-8517 (Sep 18, 1990)
- 137 Woolfson et al., "Insulin to inhibit protein catabolism after injury" New England J. of Medicine 300(1):14-17 (Jan 4, 1979)

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Examiner

Bridget E. Bunner

Date Considered

7/7/03

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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